



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/631,204

07/31/2003

James E. Selis

1142-001

2183

25215

7590

08/22/2006

DOBRUSIN & THENNISCH PC
29 W LAWRENCE ST
SUITE 210
PONTIAC, MI 48326

EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,204	SELIS, JAMES E.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 29 June 2006.

Specification

1. The corrections to the specification filed on 29 June 2006 are accepted by the Examiner.

Claim Objections

2. Claim 36 is objected to because of the following informalities: it is dependent on claim 30. Claim 30 is the independent claim for the clip, not the device. Claim 36 should be dependent on the device claim 32. Remove "30" from claim 36 and insert --32--. It is noted that claim 36 has been interpreted as being dependent on claim 32, not claim 30. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-22, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowlatshahi (Patent No. 5,853,366).

Regarding claim 21 Dowlatshahi discloses a clip (marker; Figure 1A, element 10) comprising a first portion (12) that is straight and at least one additional second portion (portion opposite first portion; also referred to as element 12) that is straight and connected to the first portion (12) at an apex (16) coplanar with the first and second

portion (column 5, line 5). Figure 2A shows both portions can also be arcuate. The first and second portions (12) are adapted to permit the marker (10) to compress to fit within a tube (20) of a delivery device (100; column 10, lines 61-63) and to elastically deform from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (20) for engaging tissue (column 11, lines 32-36).

Dowlatshahi discloses the clip (10) is capable of collapsing to a reduced size and capable of resuming its original shape and size upon discharge from a guide member (column 3, lines 6-12), thus the clip is deformable and resilient. Therefore, the clip (10) of Dowlatshahi is inherently capable of unfolding upon itself about the first apex (16) by rotating greater than 90 degrees relative to an opposing portion, if the orientation of the clip (10) in the guide tube (20) is changed such that it would have to rotate greater than 90 degrees in order to resume its original size and shape. Dowlatshahi further discloses that the original shape of the clip (10) is designed to remain in a fixed position within the body (i.e. engages tissue to prevent migration; column 3, lines 9-11). Figure 7F shows the clip (10) engaging tissue and the clip (10) in a non-spiral configuration.

Regarding claim 22, one or both of the first or second portion (12) of the clip (10) of Dowlatshahi is inherently capable of rotating greater than 45 degrees about the first apex (16) at both ends of the first or second portion (12), if the orientation of the clip (10) in the guide tube (20) is changed such that one or both of the first or second portion (12) would have to rotate greater than 45 degrees in order for the clip (10) to resume its original size and shape.

Regarding claim 25, the first or second portion (12) of the clip (10) of Dowlatshahi is inherently capable of rotating greater than 90 degrees about the first apex (16) at one or more ends of the first or second portion (12), if the orientation of the clip (10) in the guide tube (20) is changed such that the first or second portion (12) would have to rotate greater than 90 degrees about the first apex (16) in order for the clip (10) to resume its original size and shape.

Regarding claim 26, the first or second portion (12) of the clip (10) of Dowlatshahi is inherently capable of rotating greater than 180 degrees about the first apex (16) at one or more ends of the first or second portion (12), if the orientation of the clip (10) in the guide tube (20) is changed such that the first or second portion (12) would have to rotate greater than 180 degrees about the first apex (16) in order for the clip (10) to resume its original size and shape.

Regarding claim 29, Dowlatshahi discloses the first, second, or both portions (12) are further configured with at least one end (Figure 1A, element 14) having a barb (column 6, lines 34-38).

5. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Esposito et al. (International Publication No. WO 00/24320).

Esposito et al. disclose a device (Figure 11, element 100) for deploying a clip (Figure 15, element 160) comprising a gripping portion (head portion; 124) attached to a hub portion (112). Figure 3 shows an alternative embodiment of the gripping portion having two opposing semicircular or substantially circular finger grips (13). Figure 12 shows a tube (140) joined with the hub portion (112); the tube (140) having defined at

Art Unit: 3731

one end portion an end hole (not labeled; Figure 14). Figure 12 further shows a driver (push rod; 132) having an actuator member (plunger; 116) in driving relation therewith. Esposito et al. disclose that upon translation of the actuator member (116), the driver (132) advances through the hub portion (112) and the tube (140) to advance the clip (160) located in the tube (140) toward and along a ramp (since guide tube 114 has a curved channel 150, and the clip 160 travels through tube 140, which is within guide tube 114) for expulsion through the respective end hole (distal end hole, not labeled). The device is free from a lock that requires unlocking to permit the actuator member (116) to operate (page 10, lines 5-9; Esposito does not discuss the step of having to unlock a lock in order to operate actuator 116).

Figure 16 shows the actuator (116) is inherently capable of requiring only one hand to operate, since all the user would have to do is push the actuator (116), which could be done with either the users palm or thumb of one hand, while using the fingers of the same hand to hold the device at the gripping portion (124).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3731

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi.

Regarding claim 23, Dowlatshahi discloses a clip (10) as described above, including a third portion (also 12) that is straight, arcuate, or a combination thereof (see Figure 3A). Dowlatshahi also discloses the clip (10) is capable of collapsing to a reduced size and capable of resuming its original shape and size upon discharge from a guide member (column 3, lines 6-12), thus the clip (10) is deformable and resilient. Therefore, the third portion (12) of the clip (10) of Dowlatshahi is inherently capable of rotating greater than 45 degrees about an apex (16), if the orientation of the clip (10) in the guide tube (20) is changed such that it would have to rotate greater than 45 degrees in order for the clip (10) to resume its original size and shape. Dowlatshahi further discloses that the original shape of the clip (10) is designed to remain in a fixed position within the body (i.e. engages tissue to prevent migration; column 3, lines 9-11). Figure 7F shows the clip (10) engaging tissue and the clip (10) in a non-spiral configuration.

Dowlatshahi does not disclose the third portion (12) forms a second apex with the first or second portion (12). It would have been obvious to a person of ordinary skill in the art the time the invention was made to provide a clip with a second apex (for example, "N" shaped vice "V" shaped). Applicant has not disclosed a clip with a second apex provides an advantage, is used for a particular purpose, or solves a stated

problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to work equally well with a clip with that has a second apex because the function of the clip is to mark a biopsy site for radiographic analysis, and its shape does not affect this function. Therefore, it would have been obvious to modify the shape of the clip of Dowlatshahi to obtain the invention as specified in claim 23.

Regarding claim 24, Dowlatshahi does not disclose the first, second, and third portions (12) rotate greater than 90 degrees about the second apex. It would have been obvious to one having ordinary skill in the art at the time the invention was made to orient the clip such that the first, second, and third portions (12) rotate greater than 90 degrees about the second apex, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

9. Claims 27-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Sirimanne et al. (Patent No. 6,371,904 B1).

Regarding claim 27, Dowlatshahi discloses a clip (10) as described above. Dowlatshahi also discloses the clip (10) elastically deforms relative to the apex (see Figure 6B for illustration) from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (140). Dowlatshahi does not disclose that the clip is a wire. Like Dowlatshahi, Sirimanne et al. disclose a marker (or "clip"; Figures 1A-1K, element 158) that elastically deforms upon exiting a delivery tube (Figures 6B and 6D). Unlike Dowlatshahi, Sirimanne et al. disclose the marker (158) can be a wire or suture (column 10, line 20) so that the marker (158) can be configured in a particular pattern within the body of the deploying device (Figure 6B, element 606; column 10, lines 24-

Art Unit: 3731

27). Sirimanne et al. also disclose the marker (158) can be made of a non-bioabsorbable radiopaque material such as stainless steel, titanium, a nickel containing metal, or a polymer (column 10, lines 54-59, and 63-66) so that it can be located by non-invasive techniques (column 10, lines 48-50). Therefore, to construct the clip (10) of Dowlatshahi from a wire made of stainless steel, titanium, a nickel containing metal, or a polymer as taught by Sirimanne et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (10) can be configured into a shape that is desired by the user while being detectable after deployment by non-invasive imaging techniques.

Regarding claim 28, Dowlatshahi discloses that the clip (10) can be assembled from two or more pieces of material if desired (column 6, lines 44-47). Dowlatshahi does not disclose that the "pieces of material" are wires. Sirimanne et al. disclose a marker (158), as described above, that can be a wire or suture (column 10, line 20) so that the marker (158) can be configured in a particular pattern within the body of the deploying device (Figure 6B, element 606; column 10, lines 24-27). Therefore, to assemble the clip (10) of Dowlatshahi, where the plurality of "pieces of material" constitute wires as taught by Sirimanne et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (10) can be configured into a shape that is desired by the user.

Regarding claim 31, Dowlatshahi does not disclose the clip (10) is formed of a single wire. Sirimanne et al. disclose a marker (158), as described above, that can be a wire or suture (column 10, line 20) so that the marker (158) can be configured in a

particular pattern within the body of the deploying device (Figure 6B, element 606; column 10, lines 24-27). Therefore, to construct the clip (10) of Dowlatshahi from a single wire as taught by Sirimanne et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (10) can be configured into a shape that is desired by the user.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Barsch (Patent No. 6,234,177 B1).

Dowlatshahi discloses a clip (10), as described above, having a largest dimension of less than about 1 cm (3 mm – 6 mm; column 6, lines 30-32) and is configured for insertion into breast tissue, since Dowlatshahi discloses the clip (10) is used to mark breast lesions (column 1, line 7), including cysts (column 1, line 19). Upon exiting the delivery device (Figure 2A, element 100), the first and second portions (12) are configured to engage the breast tissue (via a barb or similar extension) such that the clip (10) becomes substantially immobile (the barb inhibits or prevents movement; column 6, lines 34-38). Dowlatshahi also discloses the marker (10) is observable through ultrasound devices, mammography devices, or both (conventional radiographic, sonographic, thermographic, or magnetic techniques; column 5, lines 40-46).

Dowlatshahi does not disclose the material used to make the marker. Like Dowlatshahi, Barsch discloses a marker (or "clip" Figure 4A, element 42). Unlike Dowlatshahi, Barsch discloses the marker (42) may be made out of memory shape material (memory metal; column 6, lines 31-32), since memory shape materials are not susceptible to bio-degradation when deployed within a living body (column 6, lines 26-

32). Therefore, to construct the clip (10) of Dowlatshahi out of memory shape material as taught by Barsch would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (10) is not susceptible to bio-degradation.

11. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Klein et al. (International Publication No. WO 00/67833).

Esposito et al. disclose a device (100) as described above, however, Esposito et al. does not disclose a luer lock mechanism on the hub portion (112). Like Esposito et al., Klein et al. disclose a deployment device (hypodermic needle; Figure 1, element 24). Unlike Esposito et al., Klein et al. disclose a luer lock mechanism (luer taper on inner wall surface 52 of hub 42) for the attachment of the tube (needle formed of hypotube; 44) to the hub portion (42) so that the deployment device (24) would be able to withstand the high pressures required to inject suspended solids through the needle (page 4, lines 8-11). Therefore, to construct the device of Esposito et al. with a luer lock mechanism on the hub for the attachment of a needle as taught by Klein et al. would have been obvious to one of ordinary skill in art at the time the invention was made so that the deployment device would be able to withstand the high pressures required to deploy the clip (160) through the end hole and into the tissue.

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Voegele et al. (Patent No. 6,220,248 B1).

Esposito et al. disclose a device (100) as described above, however, Esposito et al. do not disclose an indicator for providing feedback. Like Esposito et al., Voegele et al. disclose a marker (Figure 18, element 61). Unlike Esposito et al., Voegele et al.

disclose an indicator for providing audible and tactile feedback, as well as an indicator window for providing physical or visual feedback so that the user has confirmation that the marker has been ejected (column 8, lines 26-29). Therefore, to construct the device (100) of Esposito et al. with an indicator providing physical or audible feedback as taught by Voegelé et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the user knows when the clip (160) has been ejected.

13. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esposito et al. in view of Dowlatshahi et al.

Regarding claim 35, Esposito et al. disclose a device (100) as described above, however, Esposito et al. do not disclose a visual indicator. Like Esposito et al., Dowlatshahi discloses a device (Figure 7B, element 50) for deploying a marker (10). Unlike Esposito et al., Dowlatshahi discloses an indicator (markings or indicia; Figure 5, element 39) on a tube (30) in order to indicate the position of the tube (39) relative to the guide member (20), and to prevent the tube (30) from being inserted to far (column 9, lines 56-61). Therefore, to provide an indicator on the device (100) of Esposito et al. as taught by Dowlatshahi would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the user with a way to determine the position of the tube (140).

Regarding claim 36, Esposito et al. do not disclose the clip (160) comprises two portions. Dowlatshahi discloses a clip (Figure 1A, element 10) having a general V-shape comprising a first portion (12) that is straight and at least one additional second

portion (portion opposite first portion; also referred to as element 12) that is straight. In this manner, the marker (10) is capable of at least partially collapsing such that the leg portions (12) shift toward each other when urged through a constricted area, such as the tube (20) of a delivery device (100), and then substantially resuming its original V-shape upon discharge from the tube (20; column 5, lines 51-62); in other words the clip (10) elastically deforms from a collapsed state to its original size and shape relative to each other upon exiting the tube (20) for engaging tissue (column 11, lines 32-36).

Therefore, to construct the clip (160) in a V-shape with two portions as taught by Dowlatshahi would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (160) can collapse to fit into a delivery device, and then expand upon exiting the device to engage tissue.

14. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Atalar et al. (Patent No. 6,549,800 B1).

Regarding claim 37, Dowlatshahi discloses a clip (marker; Figure 1A, element 10) comprising a first portion (12) that is straight and at least one additional second portion (portion opposite first portion; also referred to as element 12) that is straight and connected to the first portion (12) at an apex (16) coplanar with the first and second portion (column 5, line 5). Figure 2A shows both portions can also be arcuate. The first and second portions (12) are adapted to permit the marker (10) to compress to fit within a tube (20) of a delivery device (100; column 10, lines 61-63) and to elastically deform from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (20) for engaging tissue (column 11, lines 32-36).

Dowlatshahi discloses the clip (10) is capable of collapsing to a reduced size and capable of resuming its original shape and size upon discharge from a guide member (column 3, lines 6-12), thus the clip (10) is deformable and resilient. Therefore, the clip (10) of Dowlatshahi is inherently capable of unfolding upon itself about the first apex (16) by rotating greater than 90 degrees relative to an opposing portion, if the orientation of the clip (10) in the guide tube (20) is changed such that it would have to rotate greater than 90 degrees in order to resume its original size and shape. Dowlatshahi further discloses that the original shape of the clip (10) is designed to remain in a fixed position within the body (i.e. engages tissue to prevent migration; column 3, lines 9-11). Figure 7F shows the clip engaging tissue and the clip (10) in a non-spiral configuration.

Dowlatshahi further discloses the method of pushing an actuator (Figure 6B, element 64) and driver (62) along the inside portion of the guide member (or "needle" 20) dispensing a clip (10; column 8, lines 45-50). It is obvious the marker is inserted into a breast cyst, to mark the same, since Dowlatshahi discloses the clip (10) is used to mark breast lesions (column 1, line 7), including cysts (column 1, line 19).

Regarding claim 38, it is inherent that only one hand is required for the insertion of the needle (guide tube 20) of Dowlatshahi and the marking of the breast cyst, and it is also inherent that the device could be used ambidextrously. All the user would have to do is hold the device in the palm of their hand at element 50, and push the actuator (64) with the thumb or any other finger of the same hand. The user can also use either hand

to hold the device, rotate the device, align the distal end hole (22) with the clip placement site, and operate the actuator as described above.

Regarding claims 37 and 38, Dowlatshahi does not disclose a method of inserting a needle into a fluid filled breast cyst and removing the fluid. Atalar et al. discloses a method comprising the steps of inserting a needle into a fluid filled internal cyst (which includes breast cysts), and removing fluid from the cyst (column 12, lines 37-45) for diagnostic or treatment purposes (column 12, lines 42-44). The collapsing of the walls of the cyst is an obvious effect of removing its fluid, since the fluid is what gives the fluid filled cyst its shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method as taught by Atalar in order to be able to mark an evacuated breast cyst, in turn facilitating its diagnoses and/or treatment.

15. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Atalar et al., in further view of Esposito et al.

Dowlatshahi in view of Atalar et al. discloses a device as described above, including an actuator (64), a driver (62), and a clip (10) in the compressed state (see Figure 6B). Dowlatshahi et al. in view of Atalar et al. does not disclose the needle (20) has a gripping portion with two opposing semicircular or substantially circular finger grips. Like Dowlatshahi in view of Atalar et al., Esposito et al. disclose a device (Figure 11, element 100) for deploying a clip (Figure 15, element 160). Unlike Dowlatshahi in view of Atalar et al., Esposito et al. disclose a device (Figure 11, element 100) for deploying a clip (Figure 15, element 160) comprising a gripping portion (head portion;

124) attached to a hub portion (112). Figure 3 shows an alternative embodiment of the gripping portion having two opposing semicircular or substantially circular finger grips (13). This configuration allows the user to firmly hold the device during use (grasp; page 6, lines 3-4). Therefore, to construct the device of Dowlatshahi in view of Atalar et al. with semicircular or substantially circular grips as taught by Esposito et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to be able to firmly hold the device during use.

16. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowlatshahi in view of Atalar et al., in further view of Sirimanne et al.

Dowlatshahi in view of Atalar et al. discloses a device as described above, where the clip (10) comprises a material that is observable using ultrasound devices or mammography devices or both (conventional radiographic, sonographic, thermographic, or magnetic techniques; column 5, lines 40-46), and elastically deforms from a collapsed state to its original size and shape (column 10, lines 61-64) upon exiting the tube (20).

Dowlatshahi in view of Atalar et al. does not disclose the material of the clip (10). Like Dowlatshahi in view of Atalar et al., Sirimanne et al. disclose a marker (Figures 1A-1K, element 158). Unlike Dowlatshahi in view of Atalar et al., Sirimanne et al. disclose the marker (158) can be made of a non-bioabsorbable radiopaque material such as stainless steel, titanium, a nickel containing metal, or a polymer (column 10, lines 54-59, and 63-66) so that it can be located by non-invasive techniques (column 10, lines 48-50). Therefore, to construct the clip (10) of Dowlatshahi in view of Atalar et al. out of

stainless steel, titanium, a nickel containing metal, or a polymer as taught by Sirimanne et al. would have been obvious to one of ordinary skill in the art at the time the invention was made so that the clip (10) could be detected after deployment by non-invasive imaging techniques.

Response to Arguments

17. Applicant's arguments filed 29 June 2006 have been fully considered but they are not persuasive. Applicant states that the Examiner has not made sufficient showing of inherency of the teachings of the asserted prior art with respect to the properties Applicants have recited in their claims. In response to Applicants argument, it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 3731

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
August 7, 2006

Y
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
8/4/06